



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/961,201	09/24/2001	Vishva M. Dixit	PF335D2	6537

22195 7590 07/02/2003
HUMAN GENOME SCIENCES INC
9410 KEY WEST AVENUE
ROCKVILLE, MD 20850

EXAMINER

HUYNH, PHUONG N

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 07/02/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/961,201	DIXIT ET AL.
	Examiner	Art Unit
	Phuong Huynh	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE One MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 9/24/01; 3/11/03 .

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) _____ is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. ____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). ____ .
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ . 6) Other: ____ .

DETAILED ACTION

1. The location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1644, Group 1640, Technology Center 1600.
2. Claims 1-20 are pending.

Election/Restrictions

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-9, drawn to an isolated **polynucleotide** having at least 70% identity to SEQ ID NO: 1, the complement of said polynucleotide, polynucleotide comprising at least 15 bases of said polynucleotide, vector, host cell, and a process for producing a polypeptide encoded by said nucleic acid, classified in Class 536, subclass 23.5; Class 435, subclass 69.1, 252.33, and 320.1.
- II. Claims 10-11, drawn to a **polypeptide** comprising an amino acid sequence of SEQ ID NO: 1 and a polypeptide comprising an amino acid sequence which is at least 70% identical to SEQ ID NO: 1, classified in Class 530, subclass 350.
- III. Claim 12, drawn to a specific **agonist** to the polypeptide comprising an amino acid sequence which is at least 70% identical to SEQ ID NO: 1, classified in Class 530, subclass 399.
- IV. Claim 13, drawn to an **antibody** against a polypeptide comprising an amino acid sequence which is at least 70% identical to SEQ ID NO: 1, classified in Class 530, subclass 387.1.
- V. Claim 14, drawn to a specific **antagonist** to the polypeptide comprising an amino acid sequence which is at least 70% identical to SEQ ID NO: 1, classified in Class 530, subclass 395.

- VI. Claims 15-16, drawn to a method for the treatment of a patient having need of ICE LAP-6 comprising administering a polypeptide comprising an amino acid sequence of SEQ ID NO: 1 and a polypeptide comprising an amino acid sequence which is at least 70% identical to SEQ ID NO: 1, classified in Class 424, subclass 184.1.
- VII. Claim 17, drawn to a method for the treatment of a patient having need to inhibit ICE LAP-6 polypeptide using an antagonist that inhibit the polypeptide comprising an amino acid sequence which is at least 70% identical to SEQ ID NO: 1, classified in Class 424, subclass 184.1.
- VIII. Claim 18, drawn to a process for diagnosing disease comprising determining a mutation in the nucleic acid sequence encoding the polypeptide comprising an amino acid sequence which is at least 70% identical to SEQ ID NO: 1, classified in Class 435, subclass 91.2.
- IX. Claim 19, drawn to a diagnostic process comprising analyzing for the presence of the polypeptide comprising an amino acid sequence which is at least 70% identical to SEQ ID NO: 1, classified in Class 435, subclass 7.1.
- X. Claim 20, drawn to a method of identifying compounds which bind to and activate or inhibit a receptor for the polypeptide comprising an amino acid sequence which is at least 70% identical to SEQ ID NO: 1, classified in Class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the products as claimed differ with respect to structure and physiochemical properties. Therefore, they are patentably distinct.

Inventions of Groups VI-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods of treating using distinct product (polypeptide versus antagonist to polypeptide) and the methods of diagnosing and identifying compounds using distinct products differ with their respect to their process steps and endpoints. Therefore, they are patentably distinct.

Inventions of Groups (I-V) and Groups (VI-X) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the products as claimed can be used in materially different process such as making antibody or screening assays. Therefore, they are patentably distinct.

4. Because these inventions are distinct for the reasons given above and the searches are not co-extensive, restriction for examination purposes as indicated is proper.
5. Due to the complexity of the claimed invention an oral restriction was not made.
6. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.
7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (703) 308-4844. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

9. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phuong N. Huynh, Ph.D.

Patent Examiner

Technology Center 1600

June 30, 2003

Christina Chan
CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600